IV. Claims 11-16 are drawn to prevention or reduction of loss of bone density, classified in class 514, subclass 169+.

V. Claims 11-17 are drawn to treatment of chronic fatigue syndrome or fibromyalgia, classified in class 514, subclass 169+.

VI. Claims 18-21 are drawn to, [*sic*] pharmaceutical formulations[s] of DHEA, classified in class 514, subclass 169+.

VII. Claims 22-27 are drawn to [a] method of preparation of [a] formulation, classified in class 514, subclass 169+.

VIII. Claims 28-32 are drawn to [a] method of administering DHEA for the treatment of systemic lupus, classified in class 514, subclass 169+.

IX. Claims 28-33 are drawn to prevention or reduction of loss of bone density, classified in class 514, subclass 169+.

X. Claims 28-34 are drawn to treatment of chronic fatigue syndrome or fibromyalgia, classified in class 514, subclass 169+.

XI. Claim 35 is drawn to a method of controlling the bioavailability of a DHEA formulation, classified in class 514, subclass 169+.

Office Action, page 2. The restriction requirement is traversed in part.

In particular, Applicants traverse the restriction of claims 1-17 into five separate claims groups (Claim Groups I-V) and the restriction of claims 18-34 into five separate claim groups (Claim Groups VI-X). Applicants submit that claims 1-17 can be examined in one application without serious burden to the examiner because each of these claims shares a common element, namely a formulation comprising DHEA, at least 85% of which is the form I polymorph of DHEA. Claim 1 is a composition claim that recites this element in combination with a pharmaceutical excipient. Claim 5 is a method claim that recites mixing an excipient with DHEA, at least 85% of which is the form I polymorph. Claim 11 is a method claim that recites administering a pharmaceutically acceptable amount of DHEA to obtain an ameliorative result, wherein at least 85%of the DHEA is present as the form I polymorph. Claims 1-17 include no other independent

claims. To search claims 1-17, therefore, it would seem that the Examiner must search for pharmaceutical compositions containing DHEA, wherein the at least 85%of the DHEA is present as the form I polymorph, and consider whether they were obtained by mixing the DHEA with a solid pharmaceutical excipient (for claim 5) and whether they were administered in a pharmaceutically acceptable amount to obtain an ameliorative result (for claim 11).

Applicants note that each of the eleven claim groups identified in the Office Action classified in the same class and subclass. Thus, the Examiner does not rely on "separate status in the art" to justify the restriction requirement. Instead, the Examiner stated that the claims "are drawn to different formulation[s], method[s] of making and method[s] of use," noting that "[e]ach of them require[s] a separate database search." Office Action, page 2. Applicants do not understand why the type of search described above would require the searching of multiple databases. An explanation of this point is respectfully requested, should the Examiner maintain the restrictions among claims 1-17.

Applicants note that the burden of searching all of claims 1-17 is further limited by the repetition of the same elements in many of the dependent claim. That is, claims 2, 6, and 12 each recite that at least 90% of the DHEA is present as the form I polymorph; claims 3, 7, and 13 increase this percentage to 95%; and claims 4, 8, and 14 increase this percentage to 99%. For this additional reason, Applicants submit that claims 1-17 can be examined in one application without undue burden.

With respect to DHEA administration claims 11-17, which the Examiner divided into three different claim groups (Claim Groups III, IV, and V) based on the desired ameliorative result, Applicants respectfully submit that the restriction requirement is improper for the additional reason that the requirement restricts subject matter ***within*** claims. More specifically, as claims 11-14 are generic claims appearing in each of the three claim groups, the restriction between Claim Groups III, IV, and V, in effect, requires that single claims (*e.g.,* claim 11) be divided up and presented in several applications. This flatly contravenes accepted law. As stated by the CCPA:

> As a general proposition, an applicant has a right to have ***each claim*** examined on the merits.
>
> * * *
>
> If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the

> merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.
>
> * * *
>
> §121 provides the Commissioner with the authority to promulgate rules designed to ***restrict*** **an** ***application*** to one of several claimed inventions . . . . It does not provide a basis under the authority of the Commissioner to ***reject*** a particular ***claim*** on that same basis.
>
> * * *
>
> We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses.

In re Weber, Soder and Boksay, 198 USPQ 328, 331-332 (CCPA 1978) (emphasis added). *See also*, *In re Haas*, 179 USPQ 623, 624, 625 (CCPA 1973) (*In re Haas I*); *In re Haas*, 198 USPQ 334-337 (CCPA 1978) (*In re Haas II*). Thus, the CCPA ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim encompasses multiple independently patentable inventions. *See, In re Weber, Soder and Boksay, In re Haas I, and In re Haas II.* Indeed, the CCPA unequivocally stated that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim--no matter how broad, which means no matter how many independently patentable inventions may fall within it. *In re Weber*, at 334.

In re Weber, at 334.

Although restriction within a single claim is legally improper, the Patent Office is not required, at least initially, to specifically examine every species encompassed by a generic claim. The procedure for handling applications that include generic claims is set forth in 37 CFR § 1.146. This rule provides that "[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted ***if no claim to the genus is found to be***

allowable." As stated in MPEP § 809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141." Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable. Thus, in the present case, while a restriction requirement based on the species of ameliorative results recited in claims 15, 16, and 17 is legally improper, an election of species requirement, with claims 11-14 identified as generic claims, would not be improper.

Election of species practice strikes an appropriate balance between the interests of the Patent Office in promoting administrative efficiency and avoiding unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §112 are satisfied. *See, e.g.,* MPEP at 803.02; *In re Wolfrum* 179 USPQ 620 (CCPA, 1973); *In re Kuehl* 177 U.S.P.Q. 250 (CCPA, 1973). Unlike a restriction requirement, an election of species requirement does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications that may not capture the intended scope of the invention.

Finally, Applicants note that the CCPA has explicitly held that review of the improper restriction of a single claim is within the jurisdiction of the Board of Patent Appeals and Interferences and the federal courts. This is in contrast to the review of ordinary restriction requirements, which are not generally subject to appellate review. See, *In re* Haas I, *supra.* Because restriction of a single claim into multiple groups is tantamount to a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the decision is appealable. Accordingly, Applicants expressly reserve the right to appeal this decision to the Board of Appeals and/or the federal courts in the event that the restriction requirement is made final.

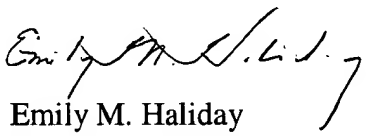
In view of the foregoing, Applicants submit that claims 1-17 can be examined together without serious burden; therefore, the restriction of claims 1-17 into Claim Groups I-V is not justified. In addition, Applicants have established that the restriction between Claim Groups III, IV, and V is legally improper. Applicants therefore respectfully request that the restriction between Claim Groups I-V be withdrawn. If this request is granted, Applicants hereby elect claims 1-17 for examination in the present application. In the event that the restriction requirement is maintained as set forth in the Office Action, Applicants provisionally elect Claim Group I with traverse. If the

Examiner agrees that some, but not all, of Claim Groups I-V can be rejoined, Applicants provisionally elect Claim Group I and any claim groups joined therewith.

Claims 18-34 are structured in the same manner as claims 1-17 and differ only in reciting, as the common element, a formulation comprising DHEA, at least 85% of which is the form II polymorph of DHEA. Nevertheless, the Examiner restricted claims 18-34 into five claim groups (Claim Groups VI-X) and such restriction is respectfully traversed. For at least the reasons discussed above with respect to claims 1-17, Applicants submit that claims 18-34 can be examined in one application without undue burden. Although claims 18-34 represent non-elected claims, Applicants respectfully request that the restriction between Claim Groups VI-X be withdrawn so that Applicants may pursue claims 18-34 in a single divisional application.If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-8891.

LAW OFFICES OF JONATHAN ALAN QUINE
P.O. BOX 458
Alameda, CA 94501
Tel: 510 337-7871
Fax: 510 337-7877

Respectfully submitted,



Emily M. Haliday
Reg. No: 38,903